Substitute Specification

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Translation of the Italian Patent application no. VI2003A000111.

TITLE

ELECTRONIC COAGULATION SCALPEL.

ABSTRACT

The invention relates to a method of regulating the power available at the manipulator of an electronic scalpel so as to make said manipulator adapted to be used to obtain blood clotting, said electronic scalpel being of the kind comprising at least a mains voltage rectifying circuit supplying rectified voltage to at least a radio frequency circuit adapted to emit as output a current carrier signal at a main frequency set by an oscillator, said current signal feeding said manipulator through a radio frequency transformer, wherein said method consists in applying to the manipulator a wave form resulting from the sum of the carrier wave and a modulating wave of such frequency that the energy transmitted to the tissue to be coagulated is such to raise the temperature of the tissue to be coagulated until denaturation of the fibrinogen contained therein is caused and transforming it into fibrin. The invention relates also to the electronic scalpel carrying out such a method.

FIGURE

Fig. no. 2

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ELECTRONIC COAGULATION SCALPEL.

The present invention relates to an electronic scalpel for clotting blood vessels, adapted for surgical applications.

More particularly, as it will be better pointed out in the following description, the invention relates to an electronic scalpel adapted to transfer to the manipulator an electric power and therefore an energy adapted to carry out blood clotting in blood vessels without causing collapse of the vessel wall.

It is well known that blood clotting occurs because a proteinic substance dissolved in the plasma called fibrinogen during blood clotting is organized into a fibrous stable structure called fibrin.

In this way a fibrin mesh is obtained, preventing blood to come out from the blood vessel in which it flows.

Therefore enhancement of organization of fibrinogen into fibrin means to attain the conditions for blood clotting.

Tests have shown that coagulation, that is transformation of fibrinogen into fibrin occurs when to the plasma molecules such a kinetic energy is transferred as to increase their temperature at least up to 63°C. Under these conditions fibrinogen is transformed into fibrin without collapse of the blood vessel.

If a temperature of 80-85°C is exceeded, the vessel collapses and the cells of the blood vessel wall die.

The presently available coagulation techniques carried out with electric scalpels cause a destruction of vessels creating a dead zone and moreover the electric scalpels operate with voltage values at dangerous levels sometimes of thousands of Volts.

The danger of high voltages together with the energy excess transmitted through the electric scalpels, causes destruction of the tissues of blood vessels as above mentioned.

Effected tests highlighted that the cells undergoing the action of the electronic scalpel, are not subject to necrotic degenerations when the energy transferred to break the molecular bond of these cells is substantially equal to the energy holding together said molecular bond.

As a matter of fact whenever energy is transferred to a cellular tissue, this causes the tissue molecules to vibrate and the increase of kinetic energy is transformed into a temperature increase of said tissue.

When temperature of the cells goes over 50°C, the cells necrotize and die.

Description of the Industrial Invention being titled "ELECTRONIC COAGULATION SCALPEL".

DESCRIPTION

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As a matter of fact whenever energy is transferred to a cellular tissue, this causes the tissue molecules to vibrate and the increase of kinetic energy is

transformed into a temperature increase of said tissue.

When temperature of the cells goes over 50°C, the cells necrotize and die. Therefore it is extremely important to operate in such a way that the electronic scalpel carries out the cutting operation without producing heat in the surrounding tissue.

Moreover it was observed that the phenomenon of temperature increase does not occur when and only when the energy transferred to the tissue molecules is equal to the molecule bonding energy.

Indeed in this case the delivered energy is not used to increase the molecule kinetic energy, but only to break the bond joining the molecules to each other.

The object of the invention is to propose a method of regulating an electronic device transmitting the wave form to the manipulator of an electronic scalpel, as well as to carry out said electronic scalpel in such a way to transfer to the tissue area to be coagulated an energy substantially equal to the energy required to obtain a proteinic denaturation transforming the fibrinogen contained in plasma into fibrin without collapse of the blood vessel.

Another object is to obtain that the power transferred by the electronic scalpel is such as not to raise the temperature of the surrounding tissues to such high values as to cause collapse of the tissue of the blood vessel.

In other words an object is to obtain that the temperature transmitted by the manipulator of the electronic scalpel to the tissue to be coagulated never exceeds 70-75 °C.

Another object of the invention indeed is to limit as much as possible or even totally prevent collapse of the blood vessels and therefore their destruction because the area no longer supplied with blood naturally dies.

A further objects is to provide an electronic scalpel using relatively low voltages for the coagulation so that the sometimes occurred possibility of intestine perforation is removed even when operating far from it.

The above mentioned objects and others that will be better highlighted in the following are attained by the electronic scalpel of the invention that according to the contents of the main claim is of the kind comprising:

- a manipulator for coagulation of organic tissues and at least an electrode to close the electric circuit being part of said manipulator;
- a rectifying circuit fed by the mains voltage supplying a rectified voltage to a radio frequency circuit;

- a radio frequency circuit comprising at least an electronic switch fed by said rectified voltage and controlled by a pilot circuit emitting a generally square current wave of predetermined amplitude and frequency,

wherein said electronic scalpel is characterized in that said radio frequency circuit has an output of a wave resulting from the sum of a generally square pulsating wave and a modulating wave, said resulting wave circulating in a wide band resonant circuit at the frequency of said generally square wave, said resonant circuit consisting of at least the eddy capacity of said electronic switch and the inductance of the primary circuit of a radio frequency transformer feeding said manipulator.

Advantageously according to the invention at the manipulator one obtains at generally regular intervals, packets of waves that are resulting from the algebraic sum of a carrier wave with frequency equal to the resonant frequency of the circuit and a set of harmonics and a modulating wave with suitable frequency.

Each packet of waves available in the manipulator has an amplitude warranting a power and therefore an energy which is transferred to the cells involved in the coagulation and causing therein a light heating because the energy transmitted to said cells is different from the bonding energy of the molecules of said cells.

In this way a heating is obtained that can be in the range of 65-70-75°C but not higher than that, so as to obtain the effect of denaturation of the fibrinogen into fibrin but not necrosis of the surrounding cells.

Also advantageously the resonance frequency of the carrier wave is preferably but not necessarily chosen around 4 MHz while the modulating wave may have the mains frequency, for instance 50 or 60 Hz or a frequency of 20-30 KHz.

The presence of a spectrum of harmonics in the resulting wave causes the manipulator to transmit a power and therefore an energy to the tissue under coagulation, which is the sum of the different specific energies due to the various frequencies.

This is particularly important because at each molecule of the cellular tissue to be coagulated of different nature corresponds an ideal energy to be transmitted to reach in the present case, the correct temperature allowing transformation of the fibrinogen into fibrin without causing damages to the

other adjacent cells.

According to an embodiment of the invention, the resulting modulated wave is obtained by enabling and disabling at intermittent intervals a BUFFER circuit allowing or preventing the crystal oscillator to transmit its pulsation to the pilot circuit of the electronic switch.

Therefore in this case intermittent pulse trains are obtained, said pulse trains depending upon the frequency by which the microprocessor controlling the BUFFER circuit carries out its enabling and disabling activity.

In another embodiment of the invention the resulting wave is obtained by summing the carrier wave generated at the frequency of the crystal oscillator and supplied by the pilot circuit to the base of the electronic switch, through a partially rectified mains wave which is connected to the collector of the electronic switch.

The so called basic modulation, namely effected generating pulse trains on the pilot circuit, is particularly used for high power machines while the modulation to the collector is used for low power machines.

Further characteristics and features of the invention will be better highlighted in the following description of a particular embodiment of the invention given as an illustrative but not limiting example and shown in the accompanying sheets of drawings in which:

- Fig. 1 is block diagram of the electronic scalpel of the invention;
- Fig. 2 is a detailed illustration of the radio frequency circuit of the electronic scalpel of Fig. 1;
- Fig. 3 shows the wave form of the power available at the manipulator of the electronic scalpel referred to the various frequencies.

With references now to the figures of the drawings and more particularly to Fig. 1, one can see that the circuit of the electronic scalpel is fed by the mains voltage and is provided with an input filter **10** as a protection against the possible radio frequency noise to or from the mains.

The circuit is also provided with a transformer indicated with **11**, whose input is a voltage **101** for instance of 220V, and having a voltage output **102** reduced to about 140 or 160V.

This voltage enters the rectifying circuit **20**, that in the embodiment now to be described, where a modulation on the base of the electronic switch is effected, is a normal rectifying diode circuit with double half wave transforming the

alternated current into a pulsating rectified current which is then filtered so that at the output there is a rather high direct voltage **201** for instance of 220V, constituting the feed of the radio frequency circuit **30**.

This radio frequency circuit is better shown in Fig. 2.

The circuit in this example uses two electronic switches for instance of the MOSFET kind.

However, if an electronic scalpel requires higher cutting powers, it is possible to use three or more MOSFET components.

Each MOSFET **305** is controlled by a pilot circuit **306** fed by the voltage **302** supplied by a direct voltage stabilized power supply of know type not shown in the drawings, in which it is possible to regulate the output voltage.

The pilot circuit **306** is also regulated by a current control **310** comprising among others a microprocessor **314** for circuitry control.

More particularly the circuit **30** provides that each MOSFET **305** acts as a switch breaking the direct current coming from the output **201** of the rectifying circuit **20** and applied to the collector of each MOSFET.

Each pilot circuit **306** emits a unidirectional pulsating not alternated square wave that drives the base of each MOSFET.

The frequency of the pilot circuit **306** is kept constant through a quartz oscillator **311** having an oscillation frequency of 4 MHz connected to a BUFFER **313**.

Therefore control of MOSFET **305** occurs through a signal having an oscillation frequency equal to that of the quartz that in case of this example is 4 MHz.

The MOSFET **305** when closed interrupts the current on the leg **301** and when is open it lets the current to pass to the leg **301**.

The width of the current wave form at **301** depends on the regulation of the signal **302** connected to the pilot circuit **306**.

The regulation of the signal at **302** allows to choose the width of the output wave so as to obtain the power intended for the manipulator **41** of the electronic scalpel according to the operation to be carried out.

According to a possible embodiment of the invention the basic oscillation frequency of 4 MHz is modulated through the intervention of the microprocessor **314** being part of the current control **310** arranging to transfer to the BUFFER circuit an enabling or disabling signal of said circuit with a

frequency of 20-30 KHz and with a duty cycle less than 30%.

In this way the BUFFER circuit **310** transmits and breaks the oscillation generated by the oscillator **311** thus generating a pulse train reaching through the pilot circuit **306**, the base of the electronic switch MOSFET **305**.

The resulting wave **301** coming out from the MOSFET switches **305** is therefore a modulated wave whose amplitude is regulated by the power regulator **302**.

According to another embodiment of the invention, a modulated resulting wave may be obtained instead of acting on the interruption of the crystal oscillator **311**, by feeding the electronic switches MOSFET **305** with a voltage **201** which is no longer direct but is a partially rectified pulsating voltage (with single half wave).

In order to obtain this it is sufficient to modify the rectifying circuit **20** so that the signal **201** comes out from said circuit without the negative half wave and carries only the positive portion of the mains sinusoidal wave.

Also in this case one obtains an output current **301** from the radio frequency circuit having a resulting wave consisting of a carrier wave at 4 MHz and a modulating wave at 50-60 KHz.

As the output of the radio frequency circuit **30** is connected to the primary of the radio frequency transformer **40**, a circulating current **301** is established passing through a resonant circuit at the frequency of 4 MHz, where the capacity and inductance of the resonant circuit are given by the eddy capacity of the MOSFET **305**, the capacitor **307** of negligible reactance but acting as lock of the direct component of a voltage **201** and the inductance of the primary circuit of the transformer **40**, respectively.

According to the invention, the resonant circuit on the carrier frequency is of the wide pass-band type so as to let pass even if dampened, at least the second and the third harmonic of the carrier wave relative to the signal **301**. Preferably it is desired that the signal **301** has at least the second, the third and the fourth harmonic.

To obtain a wide pass-band resonant circuit in the embodiment of Fig. 2 a high frequency transformer was used, having a number of turns of the secondary circuit at least the double of the primary circuit.

This because as it is known, the resonance coefficient Q is given by the formula:

$$Q = \omega C_R R_E = 2\Pi f C_R R_E =$$

where f is the resonance frequency, C_R is the capacity of the resonant circuit, R_E is the equivalent Resistance of the primary circuit when to the secondary circuit a load is applied consisting for instance of the patient's body to be operated with the electronic scalpel.

As the equivalent Resistance may be expressed by the formula

$$R_E = R_C \left(\frac{N_1}{N_2}\right)^2$$

where R_C is the load resistance and N_1 and N_2 is the number of turns of the primary and secondary respectively, one can see that the resonance factor Q may be expressed by the formula

$$Q = 2\Pi f C_R R_C \left(\frac{N_1}{N_2}\right)^2$$

The formula points out that the resonance coefficient decreases when the number of the secondary turns increases relative to that of the primary turns.

The resonance coefficient may also be expressed with the formula

$$Q = F_R / B$$

Where F_R is the resonance frequency and B is the pass-band.

In the case of the invention, when it is desired to widen the pass-band of 4 MHz to 8 MHz, 12 MHz and 16 MHz, in the resonant circuit a transformer is inserted with a suitable number of turns so that the resonance coefficient be lower than 1, preferably between 0,4 and 0,6.

The modulating wave also circulating on the resonant circuit at the frequency of the carrier wave, generates several waves with a frequency out of resonance. For this reason the resulting wave is rich of waves out of resonant frequency causing the effect to increase the temperature of the blood tissue to be coagulated. These waves out of resonance frequency may be transferred to the manipulator because the resonance coefficient of the resonant circuit is sufficiently low.

With these characteristics of wide pass-band of the resonant circuit, the secondary current signal of the transformer at **401** takes the form shown in Fig. 3. Checking the wave form of Fig. 3, one can see that at 4, 8, 12 and 16 MHz there are power peaks that are the interesting ones and are transferred to the scalpel manipulator with the above mentioned effects.

More particularly it was observed that the clotting obtained in the blood tissues is immediate and efficient. The surrounding tissue does not undergo necrosis because the increase of temperature to 70-75°C is limited to the specific

clotting area and does not involve the area of the surrounding tissue. The transformation of fibrinogen into fibrin is almost immediate.

One can see that the current of signal **401** once the power regulator **302** is set, is controlled through a current control coming from a current sensor **308** arranged after the MOSFET **305**.

The voltage signal **309** coming from the current sensor **308** drives the current control **310** providing to limit through quick comparators controlled by the microprocessor **314**, the maximum current **401** acting with the signal **312** on the pilot circuit of the MOSFET.

In case of low impedance, as the current would rise to very high values, in the circuit there is a current limiter consisting of the inductance **402** limiting the current to the manipulator and hindering the circuit to exceed the maximum admissible current value.

The electric circuit is closed through the patient's ohmic load between two electrodes which are the manipulator **41** and a plate electrode **42**.

The plate **42** is preferably covered by a light insulating layer to avoid plate burns to the patient, which are typical of the electronic scalpel.

One can see that the electrode assembly constituted by manipulator **41** and plate **42** may also take the different form of pincers with bipolar operation.

CLAIMS

1) A method of regulating the power available at the manipulator of an electronic scalpel so as to cause said manipulator adapted to be used to obtain blood coagulation, said electronic scalpel being of the kind comprising:

- at least a rectifying circuit of the mains voltage supplying a rectified voltage to
- at least a radio frequency circuit adapted to emit as output a current carrier signal at a main frequency set by an oscillator, said current signal feeding said manipulator by a radio frequency transformer,

characterized by applying to said manipulator a wave form resulting from the sum of said carrier wave and a modulating wave of such a frequency that the energy transmitted to the tissue to be coagulated is such to rise the temperature of the tissue to be coagulated until denaturation of the fibrinogen contained in the tissue is caused for its transformation into fibrin.

2) The method according to claim 1) **characterized in that** the variation of amplitude of the wave form applied to the manipulator is generated by the variation of amplitude of the power signal (302) applied to the pilot circuit.

3) An electronic scalpel to carry out the method of claim 1) of the kind comprising:

- a manipulator (41) for clotting organic tissues and at least an electrode to close the electric circuit connected thereto;
- a rectifying circuit (20) fed by the mains voltage, supplying a voltage (201) to a radio frequency circuit;
- a radio frequency circuit (30) comprising at least an electronic switch (305) fed by said voltage (201) and controlled by a pilot circuit (306),

characterized in that said radio frequency has as output a wave resulting from the sum of a generally square carrier wave and a modulating wave, said resulting wave circulating in a wide band resonant circuit at the frequency of said carrier wave, said resonant circuit being constituted by at least the eddy capacity of said electronic switch (305), and the inductance of the primary circuit of the radio frequency transformer feeding said manipulator.

4) The electronic scalpel according to claim 3) **characterized in that** said pilot circuit (306) is connected to a control circuit (310) comprising a microprocessor (314) interrupting at predetermined intervals feeding of said

pilot circuit so that the resulting wave passing through the resonant circuit takes the form of a train of intermittent pulses, each consisting of an amplitude modulated wave.

5) The electronic scalpel according to claim 3) **characterized in that** said modulating wave is applied to the collector of said electronic switch through a mains rectified voltage wave (201) without the negative half wave.

6) The electronic scalpel according to claim 3) **characterized in that** the carrier wave has the main frequency at 4 MHz .

7) The electronic scalpel according to claim 6) **characterized in that** the pulse train of the modulating wave has a frequency of 20-30 KHz.

8) The electronic scalpel according to claim 6) **characterized in that** the modulating wave has a frequency of 50 Hz.

9) The electronic scalpel according to claim 6) **characterized in that** the modulating wave has a frequency of 60 Hz.

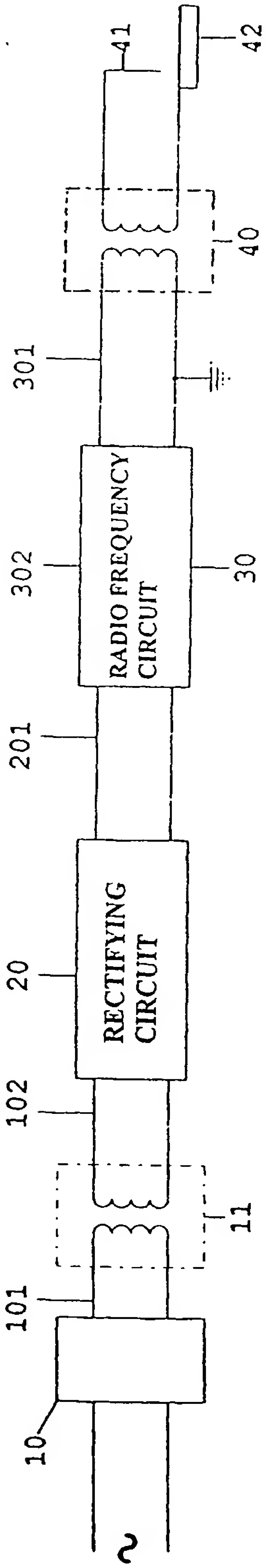

RADIO FREQUENCY CIRCUIT
RECTIFYING CIRCUIT
10
101
11
102
20
201
302
30
301
40
41
42

Fig. 1

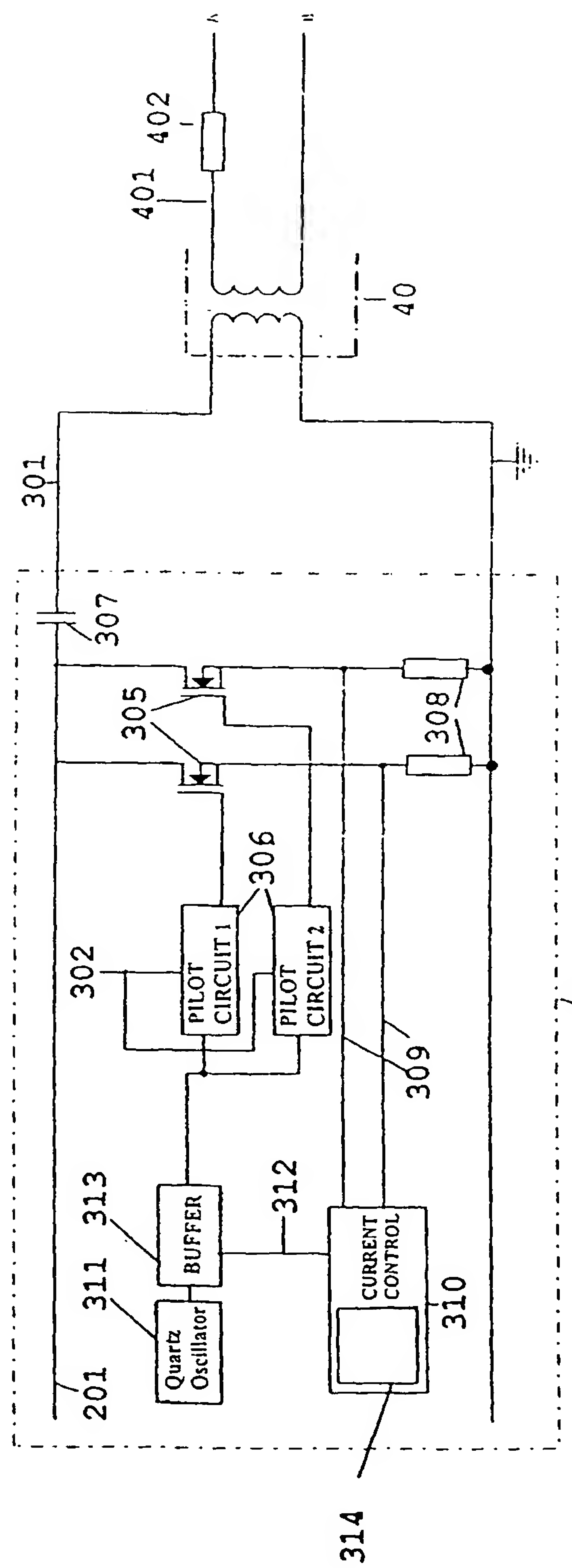
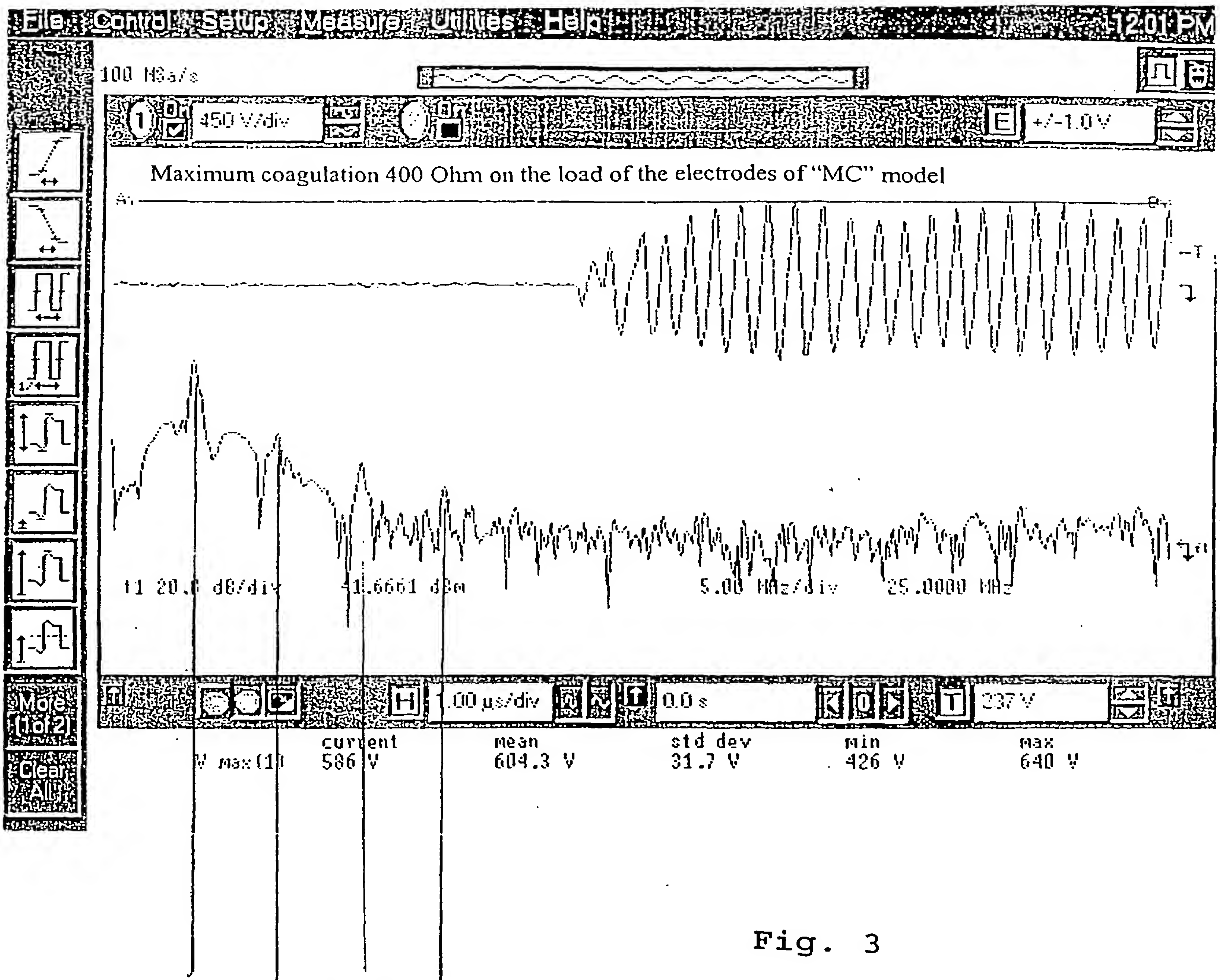

301
40
401
402
307
305
308
306
302
PILOT CIRCUIT 1
PILOT CIRCUIT 2
309
30
313
BUFFER
312
311
Quartz Oscillator
CURRENT CONTROL
310
201
314

Fig. 2



4 MHz 12 MHz

8 MHz 16 MHz

Fig. 3